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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/002,523	11/02/2001	Mark Freier	3401-125	4169

7590 10/01/2004
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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,523	FREIER ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

The disclosure is objected to because of the following informalities: Figure 3 does not show ring 18 as being an inner ring fastened within sleeve 12 on rod 6 as indicated in the specification. Figure 3 shows element 18 as being a ring radially outside of sleeve 12 instead of being within sleeve 12. Appropriate correction is required. It appears that the lead line for reference numeral 18 refers to the wrong element.

The amendment filed June 21, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The new paragraph after line 32 on page 6. There is no basis in the original disclosure for the subject matter of head 6b, narrow section 6a, shoulder 22a as well as there shapes and sizes and relative positions to each other shown in proposed new figure 4. Applicant is required to cancel the new matter in the reply to this Office Action. The proposed new figure 4 has not been entered because it contains new matter for the same reasons.

Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in

Art Unit: 3731

the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear from the disclosure how the proximal end of actuation rod 6 is releasably connected to bar 19. In particular, the structure of the receiver 22 is unclear. Further, it is unclear how the movement of bar 19 as shown at 21 affects the attachment of rod 6 to bar 19. In other words, is bar 19 moved as shown at 21 during its attachment to rod 6? If so, how does the movement of bar 19 cause or facilitate this attachment? Further, it is not seen how covering 7 can have a circumferential shape which corresponds to the circumferential shape of trough 5 and still bend upwards when pushed distally as shown in figure 2. Although a flat strip may bend as shown in figure 2, a strip which is curved in cross-section would not appear to be able to so bend.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not seen how the covering can have a "circumferential shape" since it appears to be have a strip-like form. Thus, the scope of claim 10 is unclear.

Art Unit: 3731

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bookwalter (4,926,877). Bookwalter discloses hollow shank (main portion of 12), scoop 12b (which scoops tissue therein as the hollow shank is inserted into tissue and thus defines a trough) wherein an opening 28 of said trough at least partially faces said proximal end of the hollow shank (Opening 28 faces two directions, distally to the tissue to be cut and proximally to the bore 30. For example, for a person who is in a tunnel with an opening through which the person can see the outside, it is fair to say that the opening faces the person since he can see it. Similarly, opening 28 faces the tissue inside of bore 30.), handling means (at the proximal end of 12) having an actuation mechanism 18, actuating rod (main portion of 16) and covering (distal portion of 16). Bookwalter fails to disclose the actuating rod being releasably connectable with actuation mechanism 18. However, it is old and well known in this art to releasably connect parts of surgical instruments together so that they can be detached to better sterilize them or to replace them when a part becomes defective. It would have been obvious to make the connection between the actuating rod and the actuation mechanism 18 of the Bookwalter instrument releasable so that it too would have these advantages. The above well known in the art statement is taken to be admitted

Art Unit: 3731

prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03). As to claim 10, the Bookwalter trough and covering each have a circumferential shape that correspond to each other as broadly claimed (noting the curvature of members 12 and 16 which match as indicated in col. 4, lines 48-57). As to claim 11, Bookwalter discloses holding-down device 32 (which holds down blade 16 when the needle is oriented upside down from the orientation shown in figures 2 and 5) for guiding the covering (note that they are described as "guide tracks" 32) and holding the covering at the closure position (since they hold the blade 16 in position). As to claim 12, the edge at 28 is at an angle relative to the longitudinal axis of the hollow shank as seen in figure 1.

Applicant's arguments filed June 21, 2004 have been fully considered but they are not persuasive. As to the rejection under 35 U.S.C. 112, first paragraph, as well as the new matter objection under 35 U.S.C. 132, the structure shown in new figure 4 is simply not disclosed in the original disclosure. Further, this structure in new figure 4 is different than the locking structure disclosed by Tontarra (5,607,449) and Koros (5,352,235) since these later locking structures each include a keyhole shaped slot (i.e. 87, 88 in Tontarra and 415 in Koros et al.) while new figure 4 does not. As to the circumferential

Art Unit: 3731

shape of the covering as defined in claim 10, it is not seen how the covering can have a circumferential shape (i.e. a shape around its circumference) that is generally planar rather than curved in view of the meaning of the term "circumferential". As to the rejection under 35 U.S.C. 103(a), opening 28 of Bookwalter faces in two directions as set forth above. Further, Bookwalter discloses handling means (at the proximal end of 12) having an actuation mechanism 18 and actuating rod (main portion of 16) as broadly claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
9/28/04


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731